

Applicant : Cherif-Cheikh
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REMARKS

Reconsideration and withdrawal of the rejection of claims 6-8 and 22-24, in view of the remarks herein, are respectfully requested.

Claims 6-8 and 22-25 are listed as pending. Claims 1-5 were previously canceled and claims 9-21 were previously withdrawn from consideration. Claims 6-8 and 22-25 are listed as rejected.

1. The Examiner rejected claims 6-8 and 22-24 under the judicially-created doctrine of obviousness-type double patenting over U.S. Patent No. 5,695,463 issued to the Inventor named above (hereinafter "the Cherif-Cheikh prior patent") in view of U.S. Patent No. 5,242,416 issued to Hutson (hereinafter "the Hutson patent"). Applicants respectfully traverse the Examiner's ground for rejection as follows.

When determining obviousness-type double patenting, it is well established that an Examiner cannot rely on the entire disclosure of the cited patent:

In considering the question of obvious variation, the patent disclosure [i.e., the specification] may not be used as prior art...This is not meant to infer that the disclosure may not be used at all. It may, for instance, be used as a dictionary to learn the meaning of the terms of the claim. It would not be appropriate, however, to indiscriminately use all the generalities of the disclosure. It is only that which is related to and supportive of the claims of the invention that may be used to determine the scope of the claim... For it is the claim that is of importance in determining "what inventions the claims define."
(emphasis added).

See *Phillips Petroleum Co. v. U.S. Steel Corp.*, 6 USPQ2d 1065, 1090 (D. Del. 1987), *aff'd*, 9 USPQ2d 1461 (Fed. Cir 1989). See MPEP §804(III). It is, therefore, incumbent on an Examiner to focus on the claims of the cited patent and rely on the specification only to the extent required to clarify the scope of the claim at issue.

Claim 1 of the present application is directed to an injection device having, in the most simplistic terms, a housing **configured to contain a liquid or semi-solid**, a hollow needle, a plunger, a hollow sleeve and a **removable cap**. Claim 1 of the prior Cherif-Cheikh patent is directed to an injection device having a main body member (a housing), a hollow needle, a plunger, **a rod within said needle** and a hollow sleeve. The device claimed in the present application is patentably distinct from the device claimed in the prior Cherif-Cheikh patent since it does not contain a rod to push the medicament contained in the hollow needle out but does contain a removable cap to protect the both the needle and the sleeve prior to use. In addition, the device of the present application is designed to be pre-filled wherein the needle that is the subject of the Cherif-Cheikh prior patent does not have a similar capability. The three noted differences support the patentability of claim 1 over the Cherif-Cheikh prior patent and Applicant respectfully requests that the rejection of claims 6-8 and 22-24 under the judicially-created

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doctrine of obviousness-type double patenting over the Cherif-Cheikh prior patent in view of the Hutson patent be withdrawn.

Assuming *arguendo* that the Hutson patent could be combined with the Cherif-Cheikh prior patent to support an obviousness-type double patenting rejection, it does not teach or suggest either that the rod used in the prior Cherif-Cheikh injection device can be eliminated or that the housing could be configured so as to be pre-filled with a liquid or medicament.

2. The Examiner rejected claim 25 under the judicially-created doctrine of obviousness-type double patenting over U.S. Patent No. 5,695,463 issued to the Inventor named above (hereinafter "the Cherif-Cheikh prior patent") in view of U.S. Patent No. 5,399,170 issued to Whitley (hereinafter "the Whitley patent"). Assuming *arguendo* that the Whitley patent could be combined with the Cherif-Cheikh prior patent to support a rejection under the judicially-created doctrine of obviousness-type double patenting, like the Hutson patent, it fails to teach, infer or suggest the reconfiguration of the housing to hold the medicament of the removal of the rod in combination with the plunger to push the medicament out of the device and into the patient. Claim 25 is therefore patentably distinct over both the Cherif-Cheikh prior patent and the Whitley patent either separately or in combination.

3. The Examiner rejected claims 6-8 and 23-24 under 35 U.S.C. §103(a) as being unpatenable over U.S. Patent No.

5,634,906 issued to Haber et al. (hereinafter "the Haber patent") in view of the Hutson patent. The Haber patent is directed to an opaque needle shield coupled to a standard syringe used to hide said needle from the view of a patient. It should be noted that the Haber patent device is not concerned with maintaining the asepsis or sterility of the needle. The hollow housing employed by the Haber patent is designed to accommodate a medication cartridge, see col. 3, line 37, and is not configured to contain a liquid or semi-solid composition like the housing used in the device claimed by the present application. In addition, the hollow needle of the Haber patent does not extend longitudinally within the hollow housing, but only through the medication cartridge housing. See Haber patent col. 5, lines 14-16. Also, the hollow sleeve of the device claimed by the Haber patent remains stationary. Unlike the device of the present application, it is not the hollow sleeve retracting into the housing during injection, but the housing retracting into the hollow sleeve. "The axial pushing force applied...is transferred to the medication cartridge housing 26 **which in turn moves distally through the outer sleeve guard 6** towards the targeted injection site." See Haber patent col. 6, lines 8-12. After injection, "the inner anchoring sleeve and the medication cartridge housing 26 coupled thereto are simulataneously driven proximally through the outer sleeve guard 6." If the hollow sleeve of the injection device claimed in the Haber patent were

to retract into the housing, it would expose the needle to the patient contrary to the technical problem it purports to solve. Finally, the Haber patent does not claim the use of a removable cap to cover the retractable sleeve.

The Examiner asserts that since the Hutson patent teaches use of a cap on the sheath to protect the needle prior to additional use, "it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a removable cap." Applicant contends that Hutson does not teach or suggest modifying the Haber device to reconfigure the hollow housing so that it can accommodate a liquid or semi-solid composition, to extend the hollow needle throughout the hollow housing or to allow for the hollow sleeve to retract into the hollow housing. As for use of a cap, Hutson does not teach or suggest that such a cap may be similarly used on the Haber device. The Examiner has, therefore, failed to establish an element necessary to make out a *prima facie* case of obviousness, that of showing some suggestion or motivation in the prior art to combine prior art elements in order to arrive at the subject matter claimed in the instant application. When patentability turns on the question of obviousness, the search for and analysis of the prior art includes evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and combine the references relied on as evidence of obviousness. See, e.g., McGinley v. Franklin Sports, Inc., 262 F.3d 1339,

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1351-52, 60 USPQ2d 1001, 1008 (Fed. Cir. 2001) ("the central question is whether there is reason to combine [the] references," a question of fact drawing on the Graham factors). Absent such a showing, the rejections of claims 6-8 and 23-24 under 35 U.S.C. §103(a) as being unpatenable over U.S. Patent No. 5,634,906 issued to Haber et al. (hereinafter "the Haber patent") in view of the Hutson patent are obviated.

5. The Examiner rejected claim 25 under 35 U.S.C. §103(a) as being unpatenable over the Haber patent in view of the Hutson patent and U.S. Patent No. 5,399,170 issued to Whitley (hereinafter "the Whitley patent"). Claim 25 is dependent upon current claim 6 with the additional feature of a releasable lock to inhibit the movement of the plunger into the housing. Applicant adopts and restates the differences presented above with respect to the Haber and Hutson patents. Applicant agrees that the Whitley patent does teach that a locking mechanism may be incorporated into a syringe, but like Hutson, it does not address the remaining differences between the present application and the Haber patent. Applicant contends that no combination of the Haber patent with either the Hutson or Whitley patents or both results in the device as claimed in the present application. Even if it could, there is no motivation found in any of the cited references to make such a combination. Applicant adopts and restates the above section discussing the relevant legal authority.

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6. Applicant acknowledges the Examiner's withdrawal of her prior provisional acceptance of claim 6. In an effort solely to advance the prosecution of this application, Applicant has amended claim 6 to further distinguish the novel device claimed in the present application over similar devices described in the prior art. In particular, the Applicant has included the limitation that a liquid and a dry drug composition can be combined directly in the hollow housing prior to injection. This amendment which is directed to embodiment discussed at page 2, lines 28-31 of the present application does not introduce new matter.

Applicant respectfully contends that claims 6-8 and 22-25 are in condition for allowance. Prompt and favorable action is solicited.

Should Examiner Lam deem any further action is required of the Applicant to place this application in a better condition for issue, she is requested to telephone the Applicant's undersigned representative.

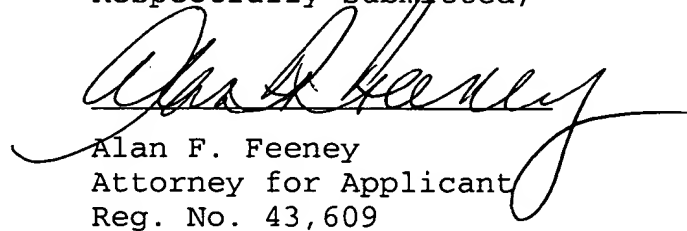
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The Commissioner hereby authorized to charge any additional fees associated with this Communication or credit any overpayment to Deposit Account No. 50-0590.

Date:

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Respectfully submitted,


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